

## **II. Remarks**

Reconsideration of this application in view of the following remarks is respectfully requested. Claims 1, 3, 8-10, 12-27, 29-32, and 35-45 are currently pending.

### **A. Double Patenting Rejection**

In the Office Action, the Examiner rejected claims 1, 3, 8-10, 12-27, 29-31 and 41-44 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-55 of U.S. Patent No. 6,375,957 to Kaiko et al. (hereinafter the '957 patent). The Examiner stated that Kaiko et al. shows an oral dosage form comprised of an opioid agonist, acetaminophen and an opioid antagonist, and allegedly shows the same elements as in the present composition. The Examiner further stated that "[i]ntended use or how a composition functions is not a basis for determining patentability of composition claims."

This rejection is traversed. It is respectfully submitted that the claims of the present application do not recite an intended use of the composition. Further, Applicants submit that claims 1-55 of the '957 patent do not claim the same composition as recited in the present claims.

Traditionally, an "intended use" in pharmaceutical patent claims would constitute, e.g., the beneficial use of the pharmaceutical in the treatment of a subject, and is typically found in the preamble. This is opposed to a limitation of the formulation itself which is included in the body of the claim. In the field of pharmaceuticals formulations, it is not uncommon for the formulation to be described and claimed by the particular capability of the formulation in a mode of use, in this case, after oral administration. Consequently, claims directed to orally administered pharmaceutical formulations will commonly recite functional limitations of the formulation. In the present application, the ratio of the amount of the components of the formulation set forth in the claims is a functional limitation which is directed to a particular capability of the dosage form when orally administered, and is not directed to the particular reason the dosage form is administered (which it is respectfully submitted would be the

“intended use” of the claimed formulation). The present claims include the functional limitation of being “aversive in physically dependent human subjects when administered in the same amount and in a higher amount than said therapeutically effective amount”. The Examiner is respectfully reminded that “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.” (Emphasis added) (See MPEP, 8<sup>th</sup> Ed. 2<sup>nd</sup> Revision, § 2173.05(g)). Accordingly, the present claims recite a functional limitation of the dosage form and do not recite an intended use, as suggested by the Examiner.

With respect to the double patenting rejection, the Examiner's attention is directed to claim 1 of the present application, which recites in part, " ...the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is ... aversive in physically dependent human subjects when administered in the same amount and in a higher amount than said therapeutically effective amount ..." (Emphasis added).

In contrast, claim 1 of the '957 patent recites in part, " ... the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is ... aversive in physically dependent human subjects when administered in the same amount or in a higher amount than said therapeutically effective amount ..." (Emphasis added).

Accordingly, Applicants respectfully submit that claims 1-55 of the '957 patent do not claim the same elements as the present claims and should not be the subject of a statutory double patenting rejection. The test for double patenting under 35 U.S.C. 101 is "whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent." (See MPEP, 8<sup>th</sup> Ed. 2<sup>nd</sup> Revision, §804, citing *In re Vogel*, 422 F.2d 438 (CCPA 1970)).

Applicants submit that it is possible to literally infringe the claims of the '957 patent, without literally infringing the present claims. For example, a claim which recites a formulation comprising element "A" or element "B" would be literally infringed by a formulation which has only element "A". However, a claim which recites a formulation comprising element "A" and element "B" would not be literally infringed by a formulation which has only element "A". This example is analogous to the present situation, as the claims of the '957 patent recite a combination product which is aversive in physically dependent human subjects when administered in the same amount or in a higher amount than said therapeutically effective amount, while the present claims recite a combination product which is aversive in physically dependent human subjects when administered in the same amount and in a higher amount than said therapeutically effective amount.

In the Office Action, the Examiner also objected to claims 32, 35-40 and 45 as being dependent upon a rejected base claims, but stated that they would be otherwise allowable if rewritten in independent form. Applicants submit that the base claims are patentable in view of the arguments presented and therefore dependent claims 32, 35-40 and 45 are patentable.

In view of the arguments presented, Applicants respectfully request that the double patenting rejection be removed.

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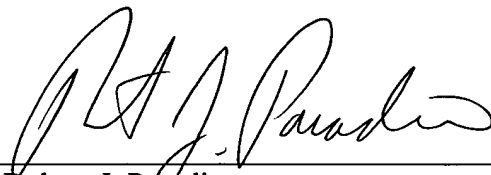
### **III. Conclusion**

It is now believed that the above-referenced rejection has been obviated and it is respectfully requested that the rejection. It is believed that all claims are now in condition for allowance.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,  
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